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MAR 13 2007

Serial No.: 10/766,139
Docket No.: PVI-5541DIVCON
Amendment dated March 13, 2007
Responsive to the Office Action dated January 29, 2007

REMARKS

Prior to the present Office Action, claims 18-19, 21-22, 24-26, 38-39, and 43-57 were pending. By way of this amendment, Applicant has added claim 58. Therefore, claims 18-19, 21-22, 24-26, 38-39, and 43-58 remain pending.

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Claim Rejections - 35 U.S.C. §101

Numerous claims stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. In response, Applicant has amended the term "tissue-engaging" to be "tissue-engagable," throughout the claims as suggested by the Examiner. Accordingly, Applicants believe the rejection under section 101 is overcome.

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Claim Rejections - 35 U.S.C. §112

Claims 38, 39, 43, and 54 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In response, Applicant has amended the term "outflow end" to be "outflow rim." The outflow rim does not define the ultimate outflow extent (end) of the base, and such terminology was used to define both the tubular base 40 (rim 50) and tissue-engaging base 104 (rim 144). Accordingly, Applicants believe the rejection under section 112 is overcome.

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Allowable Claims

Claims 38, 39 and 43 are deemed allowable pending resolution of the aforementioned section 101 and 112 rejections. Therefore, these claims are now in condition for allowance.

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Claims 49 and 54 were also deemed allowable. Claim 49 has been combined with its preceding claims (44 and 48) into new claim 58. However, based on the following remarks, Applicants believe claim 50 is allowable, and thus claim 54 remains in dependent form.

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Claim Rejections Based on Cribier

Claims 50-53, 55, and 56 stand rejected under 35 U.S.C. §102(e) as being anticipated by Cribier (USPN 6,908,481). Cribier discloses a two-part prosthetic heart valve (e.g., figures 14-15) including a tissue-engaging base that is expandable (first frame 10), and a leaflet subassembly having a support structure (second frame 10') and three valve leaflets (valvular structure 14). The procedure for implanting the two-part heart valve includes balloon expanding the base, positioning the leaflet subassembly within the base, and balloon expanding the leaflet subassembly. Naturally, the initial step of positioning the leaflet subassembly within the base includes axial movement, but the ultimate step of engaging the two parts of the heart valve involves only radially expanding the leaflet subassembly with the balloon. Indeed, it seems logical that axial movement is undesirable once the leaflet subassembly is properly positioned within the base.

Claim 50 as amended provides a plurality of discrete mating connectors on the leaflet subassembly and tissue-engagable base, one each on the leaflet subassembly and base forming a pair of mating connectors, wherein axial displacement of the leaflet subassembly toward the expanded tissue-engagable base actuates a mutual coupling mechanism on the pairs of mating connectors so as to mechanically couple the leaflet subassembly to the tissue-engagable base.

The Examiner has taken the position that Cribier discloses claim 50. In doing so, the Examiner admits that the two valve parts in Cribier are "configured to join upon axial movement and expansion (see figs. 15a-h)." Thus, the Examiner admits that the axial movement and expansion are separate steps. Indeed, the same concept was discussed in a telephone interview dated October 17, 2006 between the Examiner and the undersigned, as reflected in the Interview Summary of October 23, 2006. Claim 50 was previously amended to distinguish Garrison (U.S. 6,425,916) for the same reason, discussed below, and has been once again amended to clarify that the engagement of the two parts of the heart valve is *caused by* the axial movement.

In both Cribier and Garrison, the inner part of the valve moves axially to a positioned within the outer part, *then stops moving axially*, then is radially outwardly expanded to engage the two valve parts. Applicants respectfully request that the Examiner accord weight to the claim

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language and acknowledge that Cribier does not disclose a two-part prosthetic heart valve wherein axial displacement of one part toward another part *actuates a mutual coupling mechanism on pairs of mating connectors* so as to mechanically couple the two parts.

Moreover, claim 50 specifies pairs of mating connectors that mutually couple. This is
5 different than merely a plurality of discrete connectors, because for each connector on one part of the heart valve there must be a matching one on the other part of the heart valve with which it will mate. In contrast, Cribier states in column 20, lines 33-38 that the second (inner) frame 10' may "have an external surface that is a bit rough to allow better fixation on the first frame when expanded. The bars may also have some hooks to fasten to the first frame." This is not a
10 disclosure or suggestion of providing pairs of mating connectors, let alone ones that couple upon axial displacement toward one another.

Applicants also wish to point out that dependent claims 52-53 and 55-56 include additional features that are not disclosed or suggested by Cribier. For example, claim 52 specifies that the support structure of the leaflet subassembly comprises an elastic wireform with
15 alternating commissures and cusps, which is not present in Cribier. Claims 55 and 56 further describe the type of coupling between the mating connectors (e.g., snap fit). Applicants fail to understand how the Examiner can find that Cribier has connectors that are joined by axial compression, for example.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claim
20 50 and its dependents on the basis of Cribier.

Claim Rejections Based on Garrison

Claims 44-48, 50-53, and 55-57 stand rejected under 35 U.S.C. §102(e) as being anticipated by Garrison et al. (USPN 6,425,916), who teach a minimally invasive heart valve
25 having a valve displacer 8 that provides an anchor for a replacement cardiac valve 6 mounted to an expandable support structure 26 (i.e., stent).

First, the application of Garrison to claim 50 parallels the application of Cribier. That is,

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Garrison, like Cribier, discloses a two-part prosthetic heart valve where an inner part is positioned within an outer part and radially expanded. The engagement between the two parts is therefore not a consequence of axial displacement, but rather of radial displacement.

As mentioned above, claim 50 requires that "axial displacement of the leaflet subassembly toward the expanded tissue-engageable base actuates a mutual coupling mechanism on the pairs of mating connectors so as to mechanically couple the leaflet subassembly to the tissue-engageable base." As discussed in column 5, second and third full paragraphs, Garrison merely discloses outward protrusions on the inner (valve) member support structure 26 which engage openings in the valve displacer 8. This is clearly shown in Fig. 9, and cannot occur *as a cause of* axial displacement of the valve toward the valve displacer. Instead, the valve member 6 is radially expanded within the valve displacer 8. Applicants concede that the valve member 6 is initially axially displaced to position it within the valve displacer 8, but that is not what is recited in claim 50. Therefore, Applicants respectfully request that the Examiner remove the application of Garrison to reject claim 50 and its dependents.

Claim 44 provides a two-part prosthetic heart valve having a tissue-engageable base and a leaflet subassembly mechanically coupled therewith. The base defines a tubular body having an inflow end and an outflow rim, and leaflets of the leaflet subassembly are located outside of the tubular body *in the final product*.

The Examiner appears to view claim 44 as claiming two separate parts as an intermediate product. As a consequence, the Examiner finds that the two parts of the heart valve disclosed in Garrison "are capable" of the relative positioning as claimed. Applicants strenuously object to this reading of claim 44, which clearly requires that the final product have the leaflets outside of the tubular body of the base. To further clarify, and in an attempt to address the Examiner's reading of the claim language, claim 44 has been amended to specify that the leaflet subassembly is mechanically coupled to the tissue-engageable base to form a prosthetic heart valve. Although these are two separate components of the final prosthetic heart valve, claim 44 recites the final product, and not an intermediate product. Applicants fail to see how else a final product made

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from two components can be claimed to avoid an interpretation that separate components in the prior art "could be" re-arranged to form it. Such a theoretical construction, it seems, must be based on some indication of desirability or efficacy to be made, which is absent in Garrison.

Garrison only shows the two-part prosthetic heart valve with the valve member 6 fully disposed within the valve displacer 8 (i.e., the leaflets within the "tubular body" of the valve displacer). The Examiner cites the different arrangements of Figs. 20, 27, and 28 to suggest that the two parts may be positioned differently relative to one another. However, Fig. 20 shows the two parts coupled together with the valve member 6 (and leaflets) disposed *within* the valve displacer 8, while Figs. 27 and 28 illustrate embodiments where the valve member has barbs and is secured directly to the ascending or descending aorta. There is no mechanical coupling between the valve member and the valve displacer in the latter examples, and Applicants respectfully assert that citing these two completely different arrangements as evidence that the two valve parts could be mechanically coupled together at different relative positions is inapt. Claim 44 pertains to a two-part prosthetic heart valve where the parts are mechanically coupled together, not where they are separately implanted.

Applicants assert that claim 44 and its dependents are allowable over Garrison.

Claim Rejections Based on the Combination of Cribier and Garrison

Claims 18-19, 21-22, and 24-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cribier in view of Garrison. Applicants have amended claim 18 to include mechanical coupling members as in allowable claim 49. Based on the indication of claim 49 as allowable, Applicants believe that the addition of these same coupling members to the two-part valve of claim 18 also places it into condition for allowance.

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Based on the foregoing amendments and remarks, Applicants believe that claims 18-19, 21-22, 24-26, 38-39, and 43-58 are in condition for allowance. If there is any further hindrance to allowance, the Examiner is encouraged contact the undersigned by telephone.

5 **Fees Due to File This Amendment**

The aforementioned amendments have resulted in one additional independent claim (now 5 independent and 25 total claims). Please charge the fee of \$250 (\$200 + \$50) for the additional claim to Deposit Account No. 50-1225.

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Date: March 13, 2007

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Respectfully submitted,



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